GENRX ALL PURPOSE CLEANSING- dimethicone lotion
PureTek Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredient

Dimethicone 1.75%

Purpose

Skin Protectant

Uses

■ temporarily protects and helps relieve chapped or cracked skin
■ cleanses, moisturizes, nourishes, and protects skin
■ it can be used on face, body and perineal area

Warnings

For external use only

Do not use on

■ deep or puncture wounds ■ animal bites ■ serious burns

When using this product

■ do not get into eyes

Stop use and ask a doctor if

■ condition worsens
■ symptoms last more than 7 days or clear up and recur within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ apply cleanser to damp cloth or to skin/perineal area
■ gently wipe clean (no rinsing necessary)
■ apply as needed
■ apply GenRx protectant cream or paste as necessary

Other information

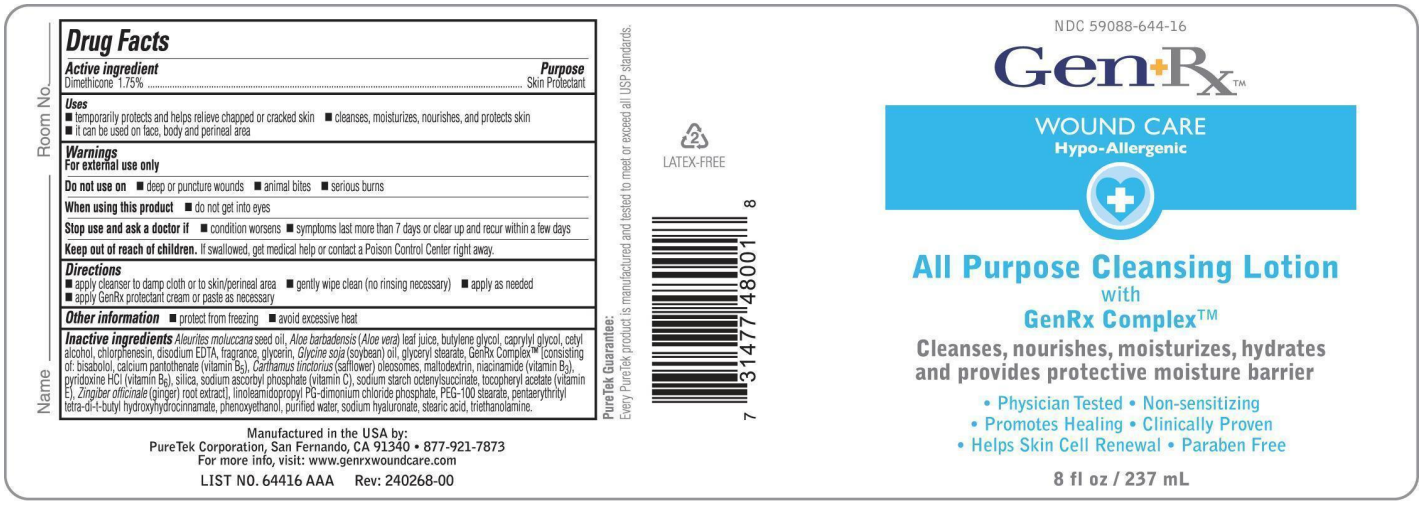
■ protect from freezing ■ avoid excessive heat

Inactive ingredients

Aleurites moluccana seed oil, *Aloe barbadensis* (*Aloe vera*) leaf juice, butylene glycol, caprylyl glycol,

cetyl alcohol, chlorphenesin, disodium EDTA, fragrance, glycerin, *Glycine soja* (soybean) oil, glyceryl stearate, GenRx Complex™ [consisting of: bisabolol, calcium pantothenate (vitamin B_5), *Carthamus tinctorius* (safflower) oleosomes, maltodextrin, niacinamide (vitamin B_3), pyridoxine HCl (vitamin B_6), silica, sodium ascorbyl phosphate (vitamin C), sodium starch octenylsuccinate, tocopheryl acetate (vitamin E), *Zingiber officinale* (ginger) root extract], linoleamidopropyl PG-dimonium chloride phosphate, PEG-100 stearate, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, purified water, sodium hyaluronate, stearic acid, triethanolamine.

All Purpose Cleansing Lotion with GenRx Complex™ (8 oz bottle label)



GENRX ALL PURPOSE CLEANSING

dimethicone lotion

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:59088-644
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dimethicone (Dimethicone)	Dimethicone	17.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
KUKUI NUT OIL	
ALOE VERA LEAF	
BUTYLENE GLYCOL	
CAPRYLYL GLYCOL	
CETYL ALCOHOL	
CHLORPHENESIN	
EDETATE DISODIUM	
GLYCERIN	
SOYBEAN OIL	
GLYCERYL MONOSTEARATE	

LEVOMENOL	
CALCIUM PANTOTHENATE	
CARTHAMUS TINCTORIUS SEED OLEOSOMES	
MALTODEXTRIN	
NIACINAMIDE	
PYRIDOXINE HYDROCHLORIDE	
SILICON DIOXIDE	
SODIUM ASCORBYL PHOSPHATE	
.ALPHA.-TOCOPHEROL ACETATE, DL-	
GINGER	
LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	
PEG-100 STEARATE	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)	
PHENOXYETHANOL	
WATER	
HYALURONATE SODIUM	
STEARIC ACID	
TROLAMINE	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-644-16	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/08/2013	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-644), pack(59088-644), label(59088-644)